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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
UNDERDAHL, THANE E	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,777	MARSHALL, ROBERT J.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-23* is/are pending in the application.

4a) Of the above claim(s) *13-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-12 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

This office action is for the response filed by the Applicant on 3/16/07. Claims 1-3 are cancelled. Claims 4-12 and 20-22 are amended. Claims 13-19 are withdrawn. Claim 23 is new.

Response to Applicant's Arguments— 35 U.S.C § 112

In the response submitted by the applicant on 3/15/07 the 35 U.S.C § 112 rejection of claims 12 and 20 as being indefinite in view of Applicant's amendment.

Response to Applicant's Arguments— 35 U.S.C § 103

Response to Applicants Amendment

In the response submitted by the applicant on 3/15/07, the 35 U.S.C § 103 (a) rejection of claims 4-10 and 20-22 over Hastings et al. in view of Hermann et al. were considered but not found persuasive.

The Applicant argues that the combination of the references above does not teach each and every limitation of the claimed invention. In particular the Applicant does not teach a composition "for producing a stabilized DHLA compound".

The Applicant is reminded that the claims are drawn to a composition. As such the limitation "for producing a stabilized DHLA compound" is an intended use and does not impart a structural relationship, such as an additional component, to the composition (M.P.E.P. § 2111.02 II). Since compositions are defined and limited by

their components, these limitations are not further limiting and are granted no patentable weight.

The combination of Hastings and Hermann does teach the components of the composition and as such render the composition *prima facie* obvious.

Furthermore the Applicant argues that "Hastings in view of Hermann does not disclose or suggest that a composition, which is not intended to be consumed, comprising secretagogue known as Symbiotropin in a combination with 7-keto DHEA can be used to produce a stabilized DHLA compound" (Applicant's Response, page 8, paragraph 4). This argument is not commensurate with the scope of the claims since nowhere in the current claim set are the limitations of a composition "comprising secretagogue known as Symbiotropin in a combination with 7-keto DHEA" and are not given patentable weight.

Therefore the rejection remains and is repeated below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-10 and 20-22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. (U.S. Patent # 6,368,617) in view of Hermann et al. (European Journal of Pharmaceutical Sciences, 1996).

These claims 4-10 are drawn to a composition comprising three parts a) at least one live probiotic organism, R-Lipoic acid, and at least one nutritive agent. The probiotic organism can be from *Lactobacillus*, *Bifidobacterium*, *Enterococcus*, *Streptococcus thermophilus*. More specifically the microorganisms can be selected from the group consisting of: *L. acidiophilus, L. paracasei, L. fermentum, L. rhamnosus, L. johnsonii, L. plantarum, L. reuteri, L. salivarius, L. brevis, L. bulgaricus, L. helveticus, L. grasseri, L. casei, L. lactis, B. bifidum, B. breve, B. infantis, B. longum, B. lactis, E. faecium,* and *E. faecalis*.

Claim 21 is an additional composition comprising *B. longum, L. acidiophilus, E. faecium, Streptococcus thermophilus* and R-Lipoic acid, and at least one nutritive agent. Claim 22 depends from claim 21 and further comprises *B. breve, B. infantis, L. casei, L. fermentum, L. helveticus, and L. plantarum.*

Claim 20 depends from claim 4 and further limits that the probiotic organism for use in a medicament or a nutritional supplement.

Hastings et al. teach a composition in claim 11 (col 7) comprising a probiotic blend of *B. bifidum* and *L. acidophilus*, a nutrient substance such as omega-3 fatty acids and saccharides, and can further comprise alpha-lipoic acid (claim 15, col 8). While Hastings does not teach solely the (R) enantiomer of lipoic acid it is obvious to use this enantiomer from the teachings of Hermann et al.

Herman et al. teach that of the racemic forms of alpha lipoic acid, the (R) enantiomer has greater bioavailablity than the (S) enantiomer (Abstract, last 3 lines). One of ordinary skill in the art that knew of the teachings of Hermann et al. would

recognize using the enantiomerically pure (R) form of lipoic acid would improve the composition of Hastings et al. The motivation is provided by Hastings et al. who show that the bioavailability of R-lipoic acid is superior to S-lipoic acid. The reasonable expectation of success is provided by Hastings et al. who show that the composition which already includes R-lipoic in a racemic mix with S-lipoic acid can be formulated.

Hastings et al. also does not teach a composition containing all the bacteria listed in claims 21 or 22. However these bacteria are well known in the art as probiotic bacteria as supported by Mercenier et al. (Current Pharm. Design Jan. 2003) and Dunne et al. (Antonie van Leeuwnhoek, 1999). Hastings et al. already uses a probiotic blend of *B. bifidum* and *L. acidophilus*. According to M.P.E.P. § 2144.06:

> "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Since Hastings et al. already adds a probiotic blend to their composition it would be *prima facia* obvious to add other probiotic organisms to their invention. Therefore claims 4-10 and 20-22 are *prima facia* obvious over Hastings et al. in view of Hermann et al.

In the response submitted by the applicant on 3/15/07, the 35 U.S.C § 103 (a) rejection of claims 11 and 12 over Hastings et al. in view of Hermann et al. and Reddy et al. were considered but not found persuasive.

As discussed above the Applicant argues that the intended use of "a microbiological culture media for producing a stabilized DHLA" compound renders the claims non-obvious over the above three references. However as explained above and reiterated here, the limitation "for producing a stabilized DHLA compound" is an intended use and does not impart a structural relationship, such as an additional component, to the composition (M.P.E.P. § 2111.02 II). Since compositions are defined and limited by their components, these limitations are not further limiting and are granted no patentable weight.

The Applicant continues to argue that "the concentrations provided for the constituents of the microbiological culture media necessarily have criticality. Applicant has determined that such disclosed concentration are necessary to support the production of a stabilized DHLA compound" (Applicant's Argument page 9, paragraph 6). However the previous rejection stated "Absent any teaching of criticality by the Applicant concerning the amounts". The Examiner needs some type of evidence that those concentrations of the media are important for the invention and that other combinations of concentrations will not perform at a similar level. Without that evidence it is obvious that one of ordinary skill in the art would simply meet those limitations by optimizing their current formulation.

Therefore the rejection remains and is repeated below.

Claims 11 and 12 are rejected as well as new claim 23 under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. and Hermann et al. as applied to the rejections of claims 4-10 and 20-22 above and in further view of Reddy et al. (U.S. Patent # 6,080,401).

These claims further limit the composition of claim 4 by including turmeric rhizome (*curcuma longa*) as the nutritive agent.

As mentioned in the reference above, Hastings et al. in view of Hermann et al. teach a composition that comprises at least one live probiotic organism, R-lipoic acid and a nutritive agent. However these two references do not specifically teach the addition of *curcuma longa* to their composition. This is taught by Reddy et al.

Reddy et al. teach a composition that, like Hastings et al., includes a probiotic blend of *Bifidobacterium* and *Lactobacillus* (Col 9, lines 33-44) to assist in weight loss and dieting (col 4, line 12), which is the same reason as Hastings et al. Reddy et al. also adds *Curcuma longa* to the composition (col 8, line 5) as a hepatic stimulant. It would have been obvious to someone skilled in the art to add *Curcuma longa* to the composition of Hastings et al. since both inventions share a common goal for a composition to assist in a diet and also share common materials such as a probiotic blend (see M.P.E.P. § 2144.06).

While the art above teaches the components of the composition of claim 4 they do not teach the amounts limited by claim 12. However, M.P.E.P. § 2144.05 II states:

> Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Absent any teaching of criticality by the applicant concerning the amounts listed in claim 12 for the composition of claim 4, it would be *prima facie* obvious that one of ordinary skill in the art would recognize that the amounts listed in claim 12 are result effective variables whose ratio and concentration are a matter of routine optimization.

Therefore claims 11, 12 and new claim 23 are *prima facia* obvious over Hastings et al. and Hermann et al. in view of Reddy et al.

In summary no claims, as written, are allowed for this application.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for

interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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